



Guidance on Applying to be a District Registered HIE Entity

This document provides instructions to apply to be a District Registered HIE Entity. Please read prior to beginning the application process.

Application Period: Ongoing

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Department of Health Care Finance
441 4th St. NW, Suite 900S
Washington, DC 20001

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Introduction

Sections 8702 - 8707 of *Chapter 87 (Health Information Exchange) of Title 29 (Public Welfare) of the District of Columbia Municipal Regulations* (“HIE Rule”) specifies the application requirements on applying to be a District Registered HIE Entity.

This document provides guidelines on the submission of the required documents for the DC HIE Registration Application, and key administrative requirements for ongoing maintenance as a District Registered HIE Entity. HIE entities interested in applying for registration are encouraged to read the HIE Rule in its entirety prior to the submission of DC HIE Registration Application.

Part 1: Guidance on the Submission of the DC HIE Registration Application

The DC HIE Registration Application consists of the submission of a form and several required attachments. As part of the application process, HIE entities must submit existing documents or in cases where there are no existing documents, develop the required documents. Should the HIE entity need to develop a document, DHCF recommends no more than 5-10 pages (double spaced with 12-point font). Applicants that have previously adopted policies, plans, or certifications, should describe how these existing documents meet the requirements of the HIE Rule in their application submission e-mail.

Part 2: Frequently Asked Questions on Key Administrative Requirements for Ongoing Maintenance as a District Registered HIE Entity

The District Registered HIE Entities are subject to the requirements of the HIE Rule. This section of the document provides key administrative requirements and guidance under the HIE Rule by subsections that involve notification or reporting by a District Registered HIE Entity to DHCF, or that involve performing audit-related activities at the request of DHCF or other DC agencies. While DHCF has addressed most policy guidance in the HIE Rule, some policies are still under development through DC’s HIE Policy Board. If you have interest in participating in the development of these pending policy guidance, please contact dc.hie@dc.gov.

If you have any questions about the requirements for this application, please contact dc.hie@dc.gov or call 202-535-2231.

Part 1: Guidance on the Submission of the DC HIE Registration Application

1. What is the DC HIE Registration Application?

The DC HIE Registration Application consists of the following:

A screenshot of the DC HIE Registration Form, showing various fields and sections for completion.

DC HIE Registration

Form: HIE entities must complete sections A-C of this form as well as read and sign the form.

Attachments: HIE entities must submit the required attachments (A.1 through A.13) listed in this guidance document.

2. What are the instructions for attachments A.1-A.13?

If the document already exists:

- **Read** the description and instructions for the document and ensure that it accurately meets the requirements.
- **Label and save** the document with the letter, number and title of the document (e.g. A.2 Cyber-liability Insurance).

If the document does not exist:

- **Create the document** based on the description and instructions. The document must not exceed to more than 5-10 pages (double spaced with 12-point font). In addition, label and save the document with the letter, number and title of the document (e.g. A.5: Policy for reasonable notice to cease operations). All submitted documents must be final versions.
- **Request a waiver or exemption on the submission of the document** by reading and reviewing the requirements on page 12 of this document and set forth in section 8712 of the HIE Rule. If the document meets these requirements, please indicate your request for waiver or exemption in your application e-mail.

3. How to submit the DC HIE Registration Application:

- Attach the completed DC HIE Registration Form (make sure to save the content of the completed form) and all required document attachments to an e-mail
- Title the subject of the e-mail: DC HIE Registration Application
- Send e-mail to dc.hie@dc.gov

Descriptions and Instructions for Attachments

A.1: Organizational and operational information

The HIE entity, per section 8702.2 (c) of the HIE Rule, must create and/or provide the following information (please reference pages of sections that highlight the requested information if it is within a document):

- The mission and vision of the organization
- Legal structure (for-profit entity, non-profit entity [501(c)(3)], other non-profit designation)
- Governance structure (e.g. Board or other stakeholder engagements)
- A diagram that shows the structure of the HIE entity and relationships and relative ranks of the individual officers at the organization

If the document does not exist, please follow the instructions listed on page 4 of this document.

A.2: General business liability insurance and cyber liability insurance

The HIE entity or its managing business organization, per section 8702.2 (b) of the HIE Rule, must provide a copy of its general business liability insurance and cyber liability insurance for the operation of the HIE entity (please reference pages of sections that highlight the requested information if it is within a document). The HIE entity must submit the following information:

- Policy number
- Coverage limit
- Effective period
- Type of first party coverage (e.g. crisis management and identity theft response, cyber extortion, data asset protection, business interruption) and, third party coverage (e.g. network security liability, privacy liability, etc.)

If the document does not exist, please follow the instructions listed on page 4 of this document.

A.3: Third-party privacy and security audit report

The HIE entity, per section 8702.2 (e) of the HIE Rule, must provide a copy of the results of its latest third-party privacy and security audit. If the document does not exist, please follow the instructions listed on page 4 of this document.

A.4: Third-party financial audit report

The HIE entity, per section 8702.2 (g) of the HIE Rule, must provide a copy of its third-party audit report for each of the past three (3) years. This report shall come from a third-party auditor that shows no expression of doubt to the entity's ability to continue as a going concern and resulting in an unqualified opinion with regard to the HIE entity's financial statements. If the document does not exist, please follow the instructions listed on page 4 of this document.

A.5: Policy for reasonable notice to cease operations

The HIE entity, per section 8702.2 (f) of the HIE Rule, must provide a copy of the its policy for ensuring reasonable notice to participating organizations and DHCF if the HIE entity ceases its operations or

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dissolves its services in the District of Columbia (please reference pages of sections that highlight the requested information if the policy is within a document). The policy must include the following:

- Protocols for the destruction of electronic health information contained in the HIE entity's core infrastructure
- The continuation of an HIE entity's existing participation agreement during the period of transition, etc.

If the document does not exist, please follow the instructions listed on page 4 of this document.

A.6: User access control policy

The HIE entity, per section 8702.2 (j) of the HIE Rule, must provide a copy of its user access control policy (please reference pages of sections that highlight the requested information if the policy is within a document) that specifies how access is managed and who may access protected health information under what circumstances. If the document does not exist, please follow the instructions listed on page 4 of this document.

A.7: Processes and policies in response to breaches

The HIE entity, per section 8702.2 (n) of the HIE Rule, must provide a copy of its processes and policies in response to breaches (please reference pages of sections that highlight the requested information if the policy is within a document) that highlight processes and policies in place to identify, notify, and respond promptly to a HIPAA privacy breach, non-HIPAA violation, or a security threat to the breach of protected health information. If the document does not exist, please follow the instructions listed on page 4 of this document.

A.8: Incident response plan

The HIE entity, per section 8702.2 (l) of the HIE Rule, must provide a copy of its incident response plan (please reference pages of sections that highlight the requested information if the plan is within a document). The primary objective of the plan should be to manage a cybersecurity event or incident in a way that limits damage, increases the confidence of external stakeholders, and reduces recovery time and costs. If the document does not exist, please follow the instructions listed on page 4 of this document.

A.9: Policy for performance of periodic, random audits

The HIE entity, per section 8702.2 (n) of the HIE Rule, must provide a copy of its policy for performance of periodic, random audits (please reference pages of sections that highlight the requested information if the policy is within a document) that incorporates and ensures compliance with applicable state and federal laws regarding privacy and security, including consent requirements. If the document does not exist, please follow the instructions listed on page 4 of this document.

A.10: Consumer education policy

The HIE entity, per section 8702.2 (n) of the HIE Rule, must provide a copy of its consumer education policy (please reference pages of sections that highlight the requested information if the policy is within a document) on how the HIE entity provides information to health care consumers concerning the process, means, and methods of accessing their protected health information and access logs for their protected health information. The policy must include information on how a consumer can file a privacy complaint, how the HIE entity responds to the complaints, and a description of the consumer's options for opting out

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of the HIE. If the document does not exist, please follow the instructions listed on page 4 of this document.

A.11: Consumer opt-out form

The HIE entity, per section 8702.2 (k) of the HIE Rule, must provide a copy of its consumer opt-out form (please reference pages of sections that highlight the requested information if the form is within a document) that clearly provides a method for the consumer to express their consent to opt-out from sharing their health information with the HIE entity. If the document does not exist, please follow the instructions listed on page 4 of this document.

A.12: Notice of privacy practices

The HIE entity, per section 8702.2 (k) of the HIE Rule, must submit a copy of the HIE entity's notice of privacy practices (please reference pages of sections that highlight the requested information if the notice is within a document). A notice of privacy practice must describe how an entity may use and disclose the protected health information of a consumer to carry out treatment, payment or health care operations and for other purposes, including whether the entity is exchanging mental health data, that are permitted or required information by law. It also must describe a consumer's rights to access and control their protected health information. If the document does not exist, please follow the instructions listed on page 4 of this document.

A.13: Participation agreement

The HIE entity, per section 8702.2 (n) of the HIE Rule, must provide a copy of its participation agreement for the different types of participating entities (e.g. payers, providers, etc.), that clearly defines privacy and security policies that are critical in facilitating the adoption and trust by participants in the HIE entity (please reference pages of sections that highlight the requested information if the notice is within a document). If the document does not exist, please follow the instructions listed on page 4 of this document.

Part 2: Frequently Asked Questions on Key Administrative Requirements for Ongoing Maintenance as a District Registered HIE Entity

Policy Guidance

Q1: What is the policy guidance for the submission of policies governing disclosure for the secondary use of health information exchange?

A1: This section references 8703.4 of the HIE Rule which requires a District Registered HIE Entity provides DHCF with policies governing disclosure for secondary use in accordance with policy guidance published by DHCF. This policy guidance is currently under development by the DC Health Information Exchange Policy Board. Further information will be released and updated via the DHCF website. Participation in the guidance and development of this policy guidance is welcomed and encouraged.

Q2: What is the policy guidance for identifying “authorized users”?

A2: This section references 8703.7(a) of the HIE Rule which requires a District Registered HIE Entity to identify each authorized user within the participating organization and note the user's assigned unique user name in accordance with the most recent applicable guidelines issued by NIST, or other nationally recognized standards identified by DHCF. This policy guidance is currently under development by the DC Health Information Exchange Policy Board. Further information will be released and updated via the DHCF website. Participation in the guidance and development of this policy guidance is welcomed and encouraged.

Q3: What is the policy guidance for conducting audits?

A3: This section references 8704.1(b) of the HIE Rule which requires a District Registered HIE Entity conduct each audit in accordance with nationally recognized standards and methodologies as identified by DHCF. This policy guidance is currently under development by the DC Health Information Exchange Policy Board. Further information will be released and updated via the DHCF website. Participation in the guidance and development of this policy guidance is welcomed and encouraged.

Q4: What is the policy guidance on a time frame for implementing a remedial action?

A4: This section references 8705.4 (a)(2) of the HIE Rule which requires a District Registered HIE Entity provides a time frame for implementing the remedial action that is consistent with policy guidance set forth by DHCF. This policy guidance is currently under development by the DC Health Information Exchange Policy Board. Further information will be released and updated via the DHCF website. Participation in the guidance and development of this policy guidance is welcomed and encouraged.

Q5: What is the policy guidance on an organization's participation in a District Registered HIE Entity?

A5: This section references 8707.2 (a) of the HIE Rule which states that a participating organization shall provide written notice to each health care consumer no later than the first medical encounter following enrollment of the organization in a registered HIE entity, of such organization's participation with a District Registered HIE Entity, including in such organization's Notice of Privacy Practices under HIPAA. This policy guidance is currently under development by the DC Health Information Exchange Policy Board. Further information will be released and updated via the DHCF website. Participation in the guidance and development of this policy guidance is welcomed and encouraged.

Reporting Guidance

Q1: What is the reporting guidance on informing each participating organization involved in an unusual finding?

A1: This section references 8704.1(f) of the HIE Rule which requires the District Registered HIE Entity's reporting of any unusual finding to each participating organization involved in the unusual finding. This reporting guidance is currently under development by the DC Health Information Exchange Policy Board. Further information will be released and updated via the DHCF website. Participation in the guidance and development of this policy guidance is welcomed and encouraged.

Q2: What is the reporting guidance concerning notification to certain authorities of the results of a District Registered HIE Entity's investigation?

A2: This section references 8705.3 (d) of the HIE Rule which establishes requirements concerning notification to certain authorities of the results of a District Registered HIE Entity's investigation. Under these provisions, upon the completion of an investigation, a District Registered HIE Entity must:

- Make a written finding describing the results of the investigation and provide a copy to the following entities within thirty (30) calendar days: District of Columbia Department of Health Care Finance, Office of the Attorney General, and the Office of Healthcare Privacy and Confidentiality.

Q3: What is the reporting guidance concerning notification to authorities in the event of a breach or violation, and applicable HIPAA notification requirements HIPAA Breach and Non-HIPAA Breach notifications?

A3: This section references 8706.3, 8706.6, 8706.7 of the HIE Rule which establishes requirements concerning notification to certain authorities in the event of a breach or violation, in addition to applicable HIPAA notification requirements.

Section 8706.3. If an investigation under 8705 of the HIE Rule concluded that there was a HIPAA breach or non-HIPAA violation, in addition to applicable HIPAA notification requirements, immediately following the investigation finding, the HIE entity must notify:

- The person who notified the District Registered HIE Entity of the potential HIPAA breach or non-HIPAA violation, if applicable, and to the extent permitted by HIPAA and other federal and District privacy laws;
- Any participating organization that has provided health information regarding the health care consumer involved;
- Each health care consumer whose PHI or sensitive health information was inappropriately accessed or disclosed due to a HIPAA breach or non-HIPAA violation; and,
- The DHCF Privacy Officer and the District of Columbia Office of the Attorney General.

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Section 8706.6. A District Registered HIE Entity, its participating organizations, or its representative should provide notification to appropriate authorities following a HIPAA breach or non-HIPAA violation within sixty (60) days from the discovery of the breach or from the date that the Registered HIE Entity should have reasonably discovered the breach, as follows:

- Report all violations of federal or District privacy or security law to those federal or District authorities to which reporting such violation is required by applicable law; and
- Send a copy of such report to the DHCF Privacy Officer and the District of Columbia Office of the Attorney General, Office of Healthcare Privacy and Confidentiality.

Section 8706.7. If DHCF is notified of a breach under 8706.6, DHCF will forward such notification to the District of Columbia Office of the Attorney General, Office of Healthcare Privacy and Confidentiality, within thirty (30) calendar days after receipt of the notification.

District Registered HIE Entity Term

Q1: How long is the District Registered HIE Entity term?

A1: The District Registered HIE Entity status is awarded for a term of three (3) years.

Q2: How does a District Registered HIE Entity renew its status post its three-year term?

A2: The DC HIE Registration Renewal Application consists of the following:

- DC HIE Renewal Registration Form- HIE entities must complete sections A-C of this form as well as read and sign the form.
- Attachments- HIE entities must submit the required attachment (A.1 through A.13) listed in this guidance document.

To renew for participation as a District Registered HIE Entity, the Entity must demonstrate its continued compliance with requirements set forth in the HIE Rule by providing the following information in a form and manner specified by DHCF:

- Any changes to information submitted with regard to the items set forth in section 8702.2 that affect the veracity of a prior submission;
- Results of a scheduled audit performed in compliance with section 8704 of the HIE Rule; and,
- Documentation of compliance with additional requirements as set forth by DHCF in policy guidance.
- The applicant will need to submit another application and will have to undergo another technical review of the application for renewal. The applicant will need to provide all the documentation that was previously mentioned above, as well as complete a different application form.

Exemptions

Q1: In what scenarios does DHCF exempt a HIE entity from requirements in the HIE Rule?

A1: In scenarios when an exemption will not pose substantial risks to the privacy or security of health care consumers, and:

- The HIE entity's infrastructure does not allow the HIE Entity to maintain compliance with a section of the HIE Rule; or
- The requirements in the HIE Rule would cause an undue burden or hardship on the HIE Entity.

Q2: How can a HIE entity request an exemption for the requirements in the HIE Rule?

A2: A HIE entity can request a one (1) year exemption from requirements set forth in the HIE Rule. An exemption request must:

- Be written in the e-mail application to DHCF;
- Identify each specific requirement of the HIE Rule from which the HIE entity is requesting an exemption;
- Identify the requested time period of the exemption;
- State the reason for each exemption request; and
- Include information that justifies the exemption request.

Q3: How long will it take DHCF to respond to a HIE entity on the status of their exemption request and what types of actions will DHCF take?

A3: Within forty-five (45) days after receipt of complete information from an applicant requesting an exemption, applying for District Registered and or Designated HIE Entity, DHCF will take one of the following actions:

- Grant the exemption by providing written notification; or
- Deny the exemption request by providing written notification that enumerates the reasons for the denial to the HIE entity.

For good cause shown, DHCF may renew a one (1)-year exemption for an additional one (1) year period, as requested by the HIE entity.

Q4: Are there any exemption requests that are excluded?

A4: An exemption may not be made for any requirements within the HIE Rule that is otherwise required of District Registered and or Designated HIE Entity by federal or other District law.

Oversight and Enforcement

DHCF will take enforcement actions as necessary, including the suspension or revocation of a District Registered and or Designated HIE Entity status in accordance with the requirements set forth below:

- When DHCF is considering suspension or revocation of an HIE entity's District Registered and or Designated HIE Entity status as set forth in section 8711, all investigatory data that are collected, created, or maintained related to the suspension or revocation are classified as confidential data on persons and as protected nonpublic data; and
- DHCF may disclose data classified as protected nonpublic or confidential under section 8711.1 (a) if disclosing the data, as permissible under 45 C.F.R. § 164.512(j), will protect the health, privacy, or safety of health care consumers.

Q1: In what situations or scenarios, does DHCF revoke or suspend a District Registered and or Designated HIE Entity's status?

A1: DHCF may suspend or revoke a District Registered and or Designated HIE Entity status issued to an HIE entity or issue a requirement for corrective action if DHCF finds that:

- The HIE entity is operating outside of nationally recognized standards identified by DHCF in policy guidance, or in a manner contrary to that described in any other information submitted under sections 8702.2 and 8708.5, unless amendments to the submissions have been filed with and approved by DHCF;
- The HIE entity is unable to fulfill its obligations to furnish comprehensive HIE services as required under its agreements with DHCF or with its participating organizations;
- The HIE entity is no longer financially solvent or may not reasonably be expected to meet its obligations to DHCF or its participating organizations;
- The HIE entity, or any person acting with its sanction, has advertised or merchandised its services in an untrue, misleading, deceptive, or unfair manner;
- The continued operation of the HIE would pose risks to its participating organizations or the privacy and security of health care consumers served by the participating organizations;
- The HIE entity improperly discloses any PHI, or health information derived from PHI, that is available through the registered or designated HIE entity's infrastructure, except as consistent with or otherwise permitted by the HIE Rule and applicable federal or District law; and
- The HIE entity has otherwise failed to substantially comply with the requirements of the HIE Rule or other applicable federal or District law.

DHCF retains its authority to enforce other generally applicable Medicaid requirements outlined in District laws and regulations, as applicable to District Registered and or Designated HIE Entities.

Q2: How will DHCF notify the HIE entity of a corrective action, suspension, or revocation of an HIE entity's District Registered and or Designated HIE Entity status?

A2: DHCF will notify the HIE entity in writing stating the grounds for the action taken. Notice will include:

- A reference to the regulatory basis for the action;
- A description of the findings of fact regarding the violations with respect to which the action is proposed;
- The nature of the action;
- Any circumstances that were considered in determining the amount of the proposed action;
- Instructions for responding to the notice, including a statement of the HIE entity's ability to request administrative review and date which response or corrective action must occur; and
- The address to which the request for review must be sent.

If DHCF suspends or revokes the District Registered and or Designated HIE Entity status, the HIE entity will not, during the period of suspension or revocation, engage in any new advertising or solicitation while holding itself out as a District Registered and or Designated HIE Entity.

Q3: What does a DHCF written request for corrective action include?

A3: All suspensions of District Registered and or Designated HIE Entity status will be accompanied by a requirement for corrective action. A DHCF written request for corrective action will include:

- Nature and scope of corrective action requested;
- Date by which corrective action must be completed by the District Registered and or Designated HIE Entity; and
- Details on how DHCF will evaluate the District Registered and or Designated HIE Entity correction of underlying issues.

Q4: What is the timeline for requesting an administrative review of DHCF's action?

A4: Within thirty days (30) of receipt of notice of enforcement action from DHCF, a HIE entity may request an administrative review of the action taken by DHCF in accordance with the procedures set forth in 8713 of the HIE Rule.